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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,244	10/23/2001	Michael Z. Gilman	346B USCI	2967

7590 04/17/2003

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EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
1632	8

DATE MAILED: 04/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,244	GILMAN ET AL.	
	Examiner	Art Unit	
Ram R. Shukla	1632		
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --			
Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>1</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.			
<ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 			
Status			
1) <input type="checkbox"/> Responsive to communication(s) filed on _____. 2a) <input type="checkbox"/> This action is FINAL . 2b) <input checked="" type="checkbox"/> This action is non-final. 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims			
4) <input checked="" type="checkbox"/> Claim(s) <u>1-37</u> is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) <input type="checkbox"/> Claim(s) _____ is/are allowed. 6) <input type="checkbox"/> Claim(s) _____ is/are rejected. 7) <input type="checkbox"/> Claim(s) _____ is/are objected to. 8) <input checked="" type="checkbox"/> Claim(s) <u>1-37</u> are subject to restriction and/or election requirement.			
Application Papers			
9) <input type="checkbox"/> The specification is objected to by the Examiner. 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
Priority under 35 U.S.C. §§ 119 and 120			
13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of: <ol style="list-style-type: none"> 1.<input type="checkbox"/> Certified copies of the priority documents have been received. 2.<input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3.<input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 14) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received. 15) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.			
Attachment(s)			
1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.		4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____.	

DETAILED ACTION

1. Claims 1-37 are pending in the instant application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17, drawn to an ex vivo method of expressing a target gene in a cell within in an organism by introducing into the organism cells comprising a transcription factor construct and a target gene construct, classified in class 424, subclass 93.1.
- II. Claims 18-37, drawn to an in vivo method of expressing a target gene in a cell within in an organism comprising introducing into the organism a transcription factor construct and a target gene construct, classified in class 514, subclass 44.

3. Inventions of the groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case, the inventions of the groups I and II are related because they are directed to a two different uses of a recombinant transcription factor, an ex vivo method of expressing a candidate gene in an animal and an in vivo method of expressing a candidate gene in an animal. It is noted that methods of the groups I-II can be practiced wherein the expression of the candidate gene is under the control of another transcription factor. Likewise, as recited in groups I and II, the transcription factor can be used in materially different process, for example, for producing a candidate protein in an animal for treatment or for making a cell that produces a protein. Furthermore, the two inventions are classified in different class and subclass. Additionally, the steps of practicing the methods of groups I and II

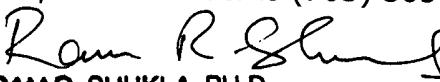
would be different, for example a method of in vitro transduction of a cell would not be used in an in vivo method.

4. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. The after-final fax number is (703) 87209307. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.



RAM R. SHUKLA, PH.D.
PATENT EXAMINER
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Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632